of the subject application, but without conceding either the need for amendment or the correctness of the Examiner's position, applicants have amended the dependency of claim 13, thereby rendering this objection moot.

Rejection Under 35 U.S.C. § 102(e)

On page 4 of the March 26, 2002 Office Action, claims 10-12 were rejected under 35 U.S.C. 102(e) as anticipated by Eicher et al. (U.S. Patent No. 6,132,755). The Examiner alleges that Eicher et al. discloses an apparatus for transdermal administration that comprises a storage compartment containing a fluid for treatment of Parkinson's disease and a dermal patch having a plurality of hollow capillaries for fluid to flow to a patient. The Examiner further alleges that Eicher et al. discloses that the flow to the patient is accomplished via the dermal patch wherein the dermal patch is attached to a portion of skin of a patient enabling the fluid to flow from the storage compartment. Applicants respectfully traverse this rejection and submit that the present application is patentable over Eicher because (1) Eicher is an improper reference under 35 U.S.C. § 102(e) and (2) Eicher does not anticipate the claimed invention.

Improper Reference

A 35 U.S.C. § 102(e), rejection can be overcome by antedating the filing date. This is accomplished if applicant's earlier foreign priority application or provisional application meets the specifications of 35 U.S.C. § 119. Additionally, the applicant's earlier foreign priority application or provisional application must "support" all of the claims in the U.S. application. See In re Gosteli, 872 F.2d 1008 (Fed. Cir. 1989).

The present application is a divisional of U.S. Application Serial No. 09/287,951, now U.S. Patent No. 6,166,081, issued December 26, 2000, which is a continuation of International Application No. PCT/IL97/00327, filed October 9, 1997. Thus, applicants respectfully submit that the 35 U.S.C. § 102(e) rejection is improper because the effective filing date of the present application is October 9, 1997, which date precedes the 35 U.S.C. § 102(e) date of the Eicher patent. The 35 U.S.C. § 102(e) of the Eicher patent is June 16, 1998. Accordingly, applicants respectfully request that this rejection be withdrawn.

No Anticipation

Under 35 U.S.C. § 102, an invention can only be anticipated by a reference that identically discloses every feature of the claimed invention. See In re Bond, 910 F.2d 831, 832, 15 USPQ2d 1566, 1567 (Fed. Cir. 1990); see also Atlas Powder Co. v. E.I. DuPont de Nemours & Co., 750 F.2d 1569, 1574 (Fed. Cir. 1984). Anticipation requires that each and every element of the claimed invention be disclosed in a single prior art reference or embodied in a single prior art device or practice. See In re Spada, 911 F.2d 705 (Fed Cir. 1990); see also Minnesota Min. & Mfg. Co. v. Johnson & Johnson Orthopedics, Inc., 976 F.2d 1559 (Fed Cir. 1992). Therefore, in order to avoid rejection for anticipation, it is only necessary to show that a claim contains at least one element not disclosed in a single prior art reference.

In column 1, lines 8-13, Eicher et al. discloses a transcorneal system for the controlled supply of drugs consisting of a device that makes it possible to administer a medicinal composition over a long period of time whilst avoiding the corneal skin layers. Column 1, lines 29-32 of Eicher et al. discloses that one essential advantage of its system is that the skin barrier for transdermally administered drugs, namely the Stratum corneum, is circumvented with the system according to the invention.

In column 1, lines 33-36, Eicher et al. discloses that it is precisely the individually different properties of the uppermost horny layer in patients that are the reason for problems such as insufficient bioavailability and allergies when active substances are administered transdermally. Thus, in column 1, lines 14-23, Eicher et al. discloses a reservoir for the drug and at least one, though typically several, micro-pins provided with capillary openings that are connected to the reservoir in such a way that the drug passes from the reservoir into the micro-pins. Upon contact with the skin, the Stratum corneum is penetrated by the micro-pins so as to provide direct access to the innervated layer of the skin. Thus, an essential advantage of the Eicher et al. system is that the skin barrier is circumvented.

On the other hand, the present invention vis-à-vis claims 10-13 discloses an apparatus for transdermal delivery of a substance for the treatment of Parkinson's disease. The present system comprises a storage compartment and a dermal patch that is in fluid communication with the

storage compartment. The dermal patch is attached to a portion of the patient's skin and the fluid flows from the storage compartment to the patient via a plurality of hollow capillaries in the dermal patch.

Eicher et al. clearly does not anticipate the instant invention in that one of Eicher et al.'s most useful advantages is the inclusion of micro-pins or micro-blades that pierce the Stratum corneum of the skin so as to directly penetrate the vascularized portions of the skin. On the other hand, the present invention comprises a dermal patch that is applied directly to the Stratum corneum. The dermal patch in the present invention does not comprise micro-pins or micro-blades; rather, the medicinal fluid is delivered to the patient via absorption through the skin.

Further, column 1, line 65–column 2, line 1-5 of Eicher et al. provide a reservoir for storing the active substance solution. A liquid conveying connection between the reservoir and the micro-pins makes it possible for the drug to be conveyed from the reservoir through the capillary openings of the micro-pins, below the Stratum corneum. In this way, the drug can be introduced directly into the bloodstream while avoiding the outer horny layers.

Alternatively, the present invention comprises a reservoir that constitutes a storage unit for fluid that reaches the skin. This fluid though, is not intended to supply drugs directly to the vascularization under the skin. When a drug is delivered directly to the vascularization, a reservoir is necessary to ensure that the quantity of the drug reaching the vascularization is prudently regulated and precisely determined. Precise determination is necessary so as to avoid reaching excess levels of the fluid in blood circulation and attendant toxicity.

In comparison, a standard patch lacks a reservoir because a drug that is not delivered directly to the blood vessel can be stored, in its entirety, in the patch without need for concern of exceeding therapeutic levels in the blood because penetration via the stratum corneum is limited and slow.

Applicants also maintain that the claimed invention is not obvious over Eicher et al. The basic considerations that apply to obviousness rejections under MPEP § 2141 are as follows:

(1) the claimed invention must be considered as a whole;

(2) the references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination;

(3) the references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention; and

(4) reasonable expectation of success is the standard by which obviousness is determined.

When the prior art itself fails to meet even one of the above criteria the cited art does not satisfy 35 U.S.C. § 103(a) and prevents the establishment of the required *prima facie* case of obviousness by the Examiner. See In re Oetiker, 977 F.2d 1443, 1445 (Fed. Cir. 1992); see also In re Rijckaert, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993). Moreover, to establish the required case of *prima facie* obviousness, the Examiner is required to demonstrate that the prior art discloses or suggests all the critical elements of the invention, without reference to applicants' specification, and that the existence of these elements enables one skilled in the art to practice the invention. See In re Vaeck, 947 F.2d 488 (Fed. Cir. 1991). It is respectfully suggested that the prior art cited by the Examiner cannot accomplish this task. Moreover, if the prior art methodology must be modified in any way to practice the instant invention the prior art citation must *also* render obvious these modifications or provide a reasonable expectation for the successful practice of the invention with the necessary modifications. See id.

In the instant case, the present invention, when considered as a whole, is not obvious over Eicher et al. The instant invention supplies medicinal fluid to a patient via a dermal patch. The medicinal fluid is stored in a storage compartment, the storage compartment is attached to a dermal patch replete with hollow capillaries, and the medicinal fluid flows through the hollow capillaries of the dermal patch for ultimate absorption through the skin.

In the Eicher et al. system, the medicinal fluid is delivered straight to the vascularized layer of the skin, bypassing the outermost layer. This is accomplished by including micro-pins or micro-blades on the patch. These micro-pins are attached to hollow capillaries through which fluid flows. The micro-pins pierce the outermost layer of the skin upon contact thereby penetrating the Stratum corneum and possibly the epidermis so as to provide direct access to the innervated layer of the skin. Eicher et al., in column 1, lines 29-36, states that an essential advantage of the system according to the invention is that the skin barrier for transdermally

administered drugs – the Stratum corneum – is circumvented. The existence of micro-pins or micro-blades is a crucial and essential element that is not present in the instant invention. In fact, Eicher et al. does not suggest the removal of micro-pins as their removal would then defeat the "piercing" purpose of the Eicher et al. system.

Accordingly, applicants maintain that the claimed invention is not obvious over Eicher et al. because it is not obvious to remove the micro-pins of the transcorneal drug-release system of Eicher et al. when dermal penetration is an advantage of the invention.

For all of the foregoing reasons, the claimed invention is neither disclosed nor suggested by the cited art. Accordingly favorable reconsideration and withdrawal of this rejection are respectfully requested.

Information Disclosure Statement

Applicants respectfully submit this Information Disclosure Statement pursuant to 37 C.F.R. §§ 1.97 and 1.98 in order to comply with the duty of disclosure under 37 C.F.R. § 1.56. The Examiner's attention is directed to the documents listed on the enclosed Form PTO-1449. The cited references constitute the art of record from parent application no. 09/287,951, now Patent No. 6,166,081, the priority of which has been claimed under 35 U.S.C. § 120. It is understood that, pursuant to M.P.E.P. § 609(I)(A)(2), such art will be considered by the Examiner.

Also, the Examiner's attention is directed to the references cited in a European Search Report for International application no. PCT/IL97/00327, dated 09 October 1997. For the Examiner's convenience, applicants provide copies of all documents cited in the European Search Report. A copy of the European Search Report is also enclosed, and the Examiner is respectfully directed thereto for a concise explanation of the relevance of the cited documents.

It is respectfully requested that the Examiner consider the above information and that a copy of the enclosed Form PTO-1449 be returned indicating that such information has been considered.

The fee for filing an Information Disclosure Statement after the issuance of an Office Action but prior to the issuance of a final action or a notice of allowance, is $180.00 according to 37 C.F.R. § 1.17(p). Authorization is hereby given to charge Deposit Account No. 19-4709 in the amount of $180.00 to cover the cost of filing the Information Disclosure Statement.

CONCLUSION

Applicants respectfully submit that this application is in condition for allowance. Early and favorable action is earnestly solicited. No fee, other than the fee for filing an Information Disclosure Statement after the issuance of the first Office Action, is deemed necessary in connection with the filing of this Amendment. However, if any fee is due, the amount of such fee may be charged to Deposit Account No. 19-4709.

Respectfully submitted,

David Schaeffer
Reg. No. 32,716

for

Lawrence Rosenthal
Registration No. 24,377
Attorney for Applicant
STROOCK & STROOCK & LAVAN, LLP
180 Maiden Lane
New York, New York 10038-4982
(212)806-5400

APPENDIX A

Below is a marked-up version of the amendment to claim 13. Deletions are indicated by bracketing and insertions are indicated by underlining.

13. Apparatus according to claim 12 [any of claims 10-12 and] comprising a regulating valve for controlling flow of said fluid from said storage compartment to said dermal patch.